Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700
clizza@saul.com

Of Counsel:

Eric W. Dittmann
Isaac S. Ashkenazi
Melanie R. Rupert
Dana Weir
M. Ryan Meuth
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166

Attorneys for Plaintiff
Helsinn Healthcare S.A.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A.,

Plaintiff,

v.

GLAND PHARMA LIMITED,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiff Helsinn Healthcare S.A. ("Helsinn" or "Plaintiff"), for its Complaint against Defendant Gland Pharma Limited ("Gland" or "Defendant"), hereby alleges as follows:

THE PARTIES

1. Plaintiff Helsinn Healthcare S.A. is a Swiss corporation having its principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.

2. Helsinn manufactures, markets, distributes, and sells innovative pharmaceutical products for improving and extending the lives of patients suffering from cancer.

3. Upon information and belief, Defendant Gland Pharma Limited is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandaimaisamma Mandal Medchal-Malkajgiri District, Hyderabad 500043, Telanagana, India.

4. Upon information and belief, Defendant Gland develops, manufactures, markets, distributes, sells, and/or imports generic versions of branded pharmaceutical products throughout the United States, including in this Judicial District.

NATURE OF THE ACTION

5. This is a civil action for patent infringement of U.S. Patent No. 8,426,450 ("the '450 patent"), U.S. Patent No. 8,895,586 ("the '586 patent"), U.S. Patent No. 9,186,357 ("the '357 patent"), U.S. Patent No. 9,403,772 ("the '772 patent"), U.S. Patent No. 9,908,907 ("the '907 patent"), U.S. Patent No. 10,208,073 ("the '073 patent"), U.S. Patent No. 10,624,911 ("the '911 patent"), U.S. Patent No. 10,717,721 ("the '721 patent"), U.S. Patent No. 10,828,297 ("the '297 patent"), and U.S. Patent No. 11,312,698 ("the '698 patent") (collectively, "the patents-in-suit").

6. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-02, and/or 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this action is an actual controversy within the Court's jurisdiction.

8. This Court may exercise jurisdiction over Defendant Gland pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*: (1) Plaintiff Helsinn's claims arise under Federal Law; (2) Gland is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Gland has sufficient contacts with the United States as a whole, including, but not limited to, by submitting or causing to be submitted various Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") and manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products throughout the United States, such that this Court's exercise of jurisdiction over Gland satisfies due process and is consistent with the U.S. Constitution and laws.

9. Alternatively, this Court has personal jurisdiction over Defendant Gland because, *inter alia*: (1) upon information and belief, Gland has purposely availed itself of the privilege of doing business in New Jersey directly or indirectly through its subsidiary, agent, and/or alter ego; (2) upon information and belief, Gland maintains pervasive, continuous, and systematic contacts with New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical products in New Jersey; (3) upon information and belief, Gland derives substantial revenue from the sale of its generic pharmaceutical products in New Jersey; and (4)

upon information and belief, Gland intends to, directly or indirectly, market, sell, or distribute Gland's ANDA Product (as defined in paragraph 25) in New Jersey.

10. Additionally, Defendant Gland has frequently submitted to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See, e.g.*, *La Jolla Pharma. Co., et al. v. Gland Pharma Ltd., et al.*, No. 22-1754 (JXN) (JBC); *Aerie Pharm. Inc., et al. v. Gland Pharma Ltd.*, No. 22-1359 (GC) (LHG); *Fresenius Kabi USA, LLC, et al. v. Gland Pharma Ltd.*, No. 20-12347 (FLW) (TJB); *Merck Sharp & Dohme B.V., et al. v. Gland Pharma Ltd.*, No. 20-2750 (CCC) (MF); *Medicure Int'l, Inc. v. Gland Pharma Ltd.*, No. 18-16246 (KM) (MAH); *Chiesi USA Inc., et al. v. Gland Pharma Ltd.*, No. 19-21204 (MCA) (MAH); *Chiesi USA Inc., Gland Pharma Ltd.*, No. 19-18565 (MCA) (MAH).

11. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(c)(3) and/or 1400(b) because Gland is a foreign corporation and may be sued in any judicial district in the United States in which Gland is subject to the court's personal jurisdiction. Gland has frequently consented to or not contested venue in this Judicial District, including in the cases identified above in paragraph 10.

THE PATENTS-IN-SUIT

12. Helsinn holds New Drug Application ("NDA") No. 210493, which was first approved by the FDA on April 19, 2018. Helsinn markets and sells the innovative fosnetupitant chloride hydrochloride / palonosetron hydrochloride pharmaceutical product that is the subject of NDA No. 210493 in the United States under the brand name Akynzeo®. Akynzeo® is available for intravenous infusion supplied as a single dose 20 mL vial containing 235 mg of fosnetupitant (equivalent to 260 mg fosnetupitant chloride hydrochloride) and 0.25 mg of palonosetron (equivalent to 0.28 mg of palonosetron hydrochloride).

13. Akynzeo® is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy.

14. The ’450 patent, titled “Substituted 4-Phenyl Pyridines Having Anti-Emetic Effect,” was duly and legally issued by the U.S. Patent and Trademark Office (“USPTO”) on April 23, 2013. Plaintiff Helsinn is the assignee of the ’450 patent. A copy of the ’450 patent is attached as Exhibit A.

15. The ’586 patent, titled “Methods of Treating Emesis,” was duly and legally issued by the USPTO on November 25, 2014. Plaintiff Helsinn is the assignee of the ’586 patent. A copy of the ’586 patent is attached as Exhibit B.

16. The ’357 patent, titled “Compositions and Methods for Treating Centrally Mediated Nausea and Vomiting,” was duly and legally issued by the USPTO on November 17, 2015. Plaintiff Helsinn is the assignee of the ’357 patent. A copy of the ’357 patent is attached as Exhibit C.

17. The ’772 patent, titled “4-(5-(2-(3,5-Bis(Trifluoromethyl)Phenyl)-N,2-Dimethylpropanamido)-4-(O-Tolyl)Pyridin-2-yl)-1-Methyl-1-((Phosphonooxy)Methyl)Piperazin-1-ium as a Neurokinin Receptor Modulator,” was duly and legally issued by the USPTO on August 2, 2016. Plaintiff Helsinn is the assignee of the ’772 patent. A copy of the ’772 patent is attached as Exhibit D.

18. The ’907 patent, titled “Substituted Piperaziniums for the Treatment of Emesis,” was duly and legally issued by the USPTO on March 6, 2018. Plaintiff Helsinn is the assignee of the ’907 patent. A copy of the ’907 patent is attached as Exhibit E.

19. The ’073 patent, titled “Solution Comprising the Chloride Hydrochloride Salt of 4-(5-(2-(3,5-Bis(Trifluoromethyl)Phenyl)-N,2-Dimethylpropanamido)-4-(O-Tolyl)Pyridin-2-yl)-1-Methyl-1-((Phosphonooxy)Methyl)Piperazin-1-ium (Fosnetupitant) and Palonosetron Hydrochloride in Combination with Dexamethasone as a Neurokinin Receptor Modulator,” was duly and legally issued by the USPTO on February 19, 2019. Plaintiff Helsinn is the assignee of the ’073 patent. A copy of the ’073 patent is attached as Exhibit F.

20. The ’911 patent, titled “Physiologically Balanced Injectable Formulations of Fosnetupitant,” was duly and legally issued by the USPTO on April 21, 2020. Plaintiff Helsinn is the assignee of the ’911 patent. A copy of the ’911 patent is attached as Exhibit G.

21. The ’721 patent, titled “Substituted Piperaziniums for the Treatment of Emesis,” was duly and legally issued by the USPTO on July 21, 2020. Plaintiff Helsinn is the assignee of the ’721 patent. A copy of the ’721 patent is attached as Exhibit H.

22. The ’297 patent, titled “Compositions and Methods for Treating Centrally Mediated Nausea and Vomiting,” was duly and legally issued by the USPTO on November 10, 2020. Plaintiff Helsinn is the assignee of the ’297 patent. A copy of the ’297 patent is attached as Exhibit I.

23. The ’698 patent, titled “Fosnetupitant Chloride Hydrochloride Having Improved Stability,” was duly and legally issued by the USPTO on April 26, 2022. Plaintiff Helsinn is the assignee of the ’698 patent. A copy of the ’698 patent is attached as Exhibit J.

24. Pursuant to § 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (“FDCA,” 21 U.S.C. § 355(b)(1)), the patents-in-suit are listed in the FDA publication titled “*Approved Drug Products with Therapeutic Equivalence Evaluations*” (commonly known as the “Orange Book”) as covering Akynzeo® and/or its use.

ACTS GIVING RISE TO THIS ACTION

25. Upon information and belief, Gland filed or caused to be filed ANDA No. 217374 with the FDA under § 505(j) of the FDCA (21 U.S.C. § 355(j)) seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg / 0.25 mg per 20 mL single-dose vials for intravenous administration ("Gland's ANDA Product") before the expiration of the patents-in-suit.

26. Upon information and belief, Gland sent a letter via Federal Express dated June 2, 2022 ("Gland's June 2 Notice Letter") providing notice of Gland's certification pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) ("Paragraph IV certification") with respect to the '450 patent, the '586 patent, the '357 patent, the '772 patent, the '907 patent, the '073 patent, the '911 patent, the '721 patent, and the '297 patent. Gland subsequently sent a second letter via Federal Express dated July 11, 2022 ("Gland's July 11 Notice Letter" and, together with Gland's June 2 Notice Letter, "Gland's Notice Letters") providing notice of Gland's Paragraph IV certification with respect to the '698 patent.

27. Gland's June 2 Notice Letter was received by Helsinn no earlier than June 7, 2022. Gland's July 11 Notice Letter was received by Helsinn no earlier than July 15, 2022. In Gland's Notice Letters, Gland represented that it had filed ANDA No. 217374 with accompanying Paragraph IV certifications to obtain approval to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States Gland's ANDA Product before the expiration of the patents-in-suit.

28. In Gland's June 2 Notice Letter, Gland alleges that each claim of the '450 patent, the '586 patent, the '357 patent, the '772 patent, the '907 patent, the '073 patent, the '911

patent, the ’721 patent, and the ’297 patent is invalid, unenforceable, and/or will not be infringed by Gland’s ANDA Product. In Gland’s July 11 Notice Letter, Gland alleges that each claim of the ’698 patent is invalid, unenforceable, and/or will not be infringed by Gland’s ANDA Product.

29. Plaintiff Helsinn has filed this action within 45 days of Helsinn’s receipt of Gland’s June 2 Notice Letter.

COUNT I – INFRINGEMENT OF THE ’450 PATENT

30. Plaintiff Helsinn re-alleges paragraphs 1-29 as if fully set forth herein.

31. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland’s ANDA Product before the expiration of the ’450 patent, Gland has infringed one or more claims of the ’450 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland’s ANDA Product, if approved by the FDA before the expiration of the ’450 patent, would infringe and/or induce and/or contribute to the infringement of one or more claims of the ’450 patent.

33. Upon information and belief, Gland was aware of the existence of the ’450 patent and that the submission of Gland’s ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the ’450 patent.

34. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland’s ANDA product before the expiration of the ’450 patent would constitute an act of infringement of one or more claims of the ’450 patent.

35. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-3 of the '450 patent.

36. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe the '450 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

37. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '450 patent, including any later expiration of exclusivity for the '450 patent to which Helsinn is or becomes entitled.

38. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT II – INFRINGEMENT OF THE '586 PATENT

39. Plaintiff Helsinn re-alleges paragraphs 1-38 as if fully set forth herein.

40. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '586 patent, Gland has infringed one or more claims of the '586 patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '586 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '586 patent.

42. Upon information and belief, Gland was aware of the existence of the '586 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '586 patent.

43. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '586 patent would constitute an act of infringement of one or more claims of the '586 patent.

44. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-21 of the '586 patent.

45. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '586 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

46. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '586 patent, including any later expiration of exclusivity for the '586 patent to which Helsinn is or becomes entitled.

47. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT III – INFRINGEMENT OF THE '357 PATENT

48. Plaintiff Helsinn re-alleges paragraphs 1-47 as if fully set forth herein.

49. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '357 patent, Gland has infringed one or more claims of the '357 patent under 35 U.S.C. § 271(e)(2)(A).

50. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '357 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '357 patent.

51. Upon information and belief, Gland was aware of the existence of the '357 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '357 patent.

52. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '357 patent would constitute an act of infringement of one or more claims of the '357 patent.

53. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112 and a blanket denial of a specific intent to provide therapeutically effective blood levels of palonosetron and netupitant, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 4, 14-16, and 52-62 of the '357 patent.

54. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's

ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '357 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

55. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '357 patent, including any later expiration of exclusivity for the '357 patent to which Helsinn is or becomes entitled.

56. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT IV – INFRINGEMENT OF THE '772 PATENT

57. Plaintiff Helsinn re-alleges paragraphs 1-56 as if fully set forth herein.

58. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '772 patent, Gland has infringed one or more claims of the '772 patent under 35 U.S.C. § 271(e)(2)(A).

59. Upon information and belief, the manufacture, use, offer for sale, sale, or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '772 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '772 patent.

60. Upon information and belief, Gland was aware of the existence of the '772 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '772 patent.

61. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of

Gland's ANDA Product before the expiration of the '772 patent would constitute an act of infringement of one or more claims of the '772 patent.

62. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-14 of the '772 patent.

63. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '772 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

64. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '772 patent, including any later expiration of exclusivity for the '772 patent to which Helsinn is or becomes entitled.

65. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT V – INFRINGEMENT OF THE '907 PATENT

66. Plaintiff Helsinn re-alleges paragraphs 1-65 as if fully set forth herein.

67. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '907 patent, Gland has infringed one or more claims of the '907 patent under 35 U.S.C. § 271(e)(2)(A).

68. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of

the ’907 patent, would infringe and/or induce and/or contribute to the infringement of one or more claims of the ’907 patent.

69. Upon information and belief, Gland was aware of the existence of the ’907 patent and was aware that the submission of Gland’s ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the ’907 patent.

70. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland’s ANDA Product before the expiration of the ’907 patent would constitute an act of infringement of one or more claims of the ’907 patent.

71. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland’s Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-6 of the ’907 patent.

72. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland’s ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the ’907 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

73. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the ’907 patent, including any later expiration of exclusivity for the ’907 patent to which Helsinn is or becomes entitled.

74. Helsinn will be irreparably harmed by Gland’s infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT VI – INFRINGEMENT OF THE '073 PATENT

75. Plaintiff Helsinn re-alleges paragraphs 1-74 as if fully set forth herein.

76. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '073 patent, Gland has infringed one or more claims of the '073 patent under 35 U.S.C. § 271(e)(2)(A).

77. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '073 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '073 patent.

78. Upon information and belief, Gland was aware of the existence of the '073 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '073 patent.

79. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '073 patent would constitute an act of infringement of one or more claims of the '073 patent.

80. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-13 of the '073 patent.

81. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's

ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '073 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

82. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '073 patent, including any later expiration of exclusivity for the '073 patent to which Helsinn is or becomes entitled.

83. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT VII – INFRINGEMENT OF THE '911 PATENT

84. Plaintiff Helsinn re-alleges paragraphs 1-83 as if fully set forth herein.

85. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '911 patent, Gland has infringed one or more claims of the '911 patent under 35 U.S.C. § 271(e)(2)(A).

86. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '911 patent, would infringe and/or induce and/or contribute to the infringement of one or more claims of the '911 patent.

87. Upon information and belief, Gland was aware of the existence of the '911 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '911 patent.

88. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of

Gland's ANDA Product before the expiration of the '911 patent would constitute an act of infringement of one or more claims of the '911 patent.

89. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1, 3, 8-11, 14, and 19-21 of the '911 patent.

90. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '911 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

91. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '911 patent, including any later expiration of exclusivity for the '911 patent to which Helsinn is or becomes entitled.

92. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT VIII – INFRINGEMENT OF THE '721 PATENT

93. Plaintiff Helsinn re-alleges paragraphs 1-92 as if fully set forth herein.

94. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '721 patent, Gland has infringed one or more claims of the '721 patent under 35 U.S.C. § 271(e)(2)(A).

95. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of

the ’721 patent, would infringe and/or induce and/or contribute to the infringement of the ’721 patent.

96. Upon information and belief, Gland was aware of the existence of the ’721 patent and was aware that the submission of Gland’s ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the ’721 patent.

97. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland’s ANDA Product before the expiration of the ’721 patent would constitute an act of infringement of one or more claims of the ’721 patent.

98. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland’s Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claim 1 of the ’721 patent.

99. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland’s ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the ’721 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

100. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the ’721 patent, including any later expiration of exclusivity for the ’721 patent to which Helsinn is or becomes entitled.

101. Helsinn will be irreparably harmed by Gland’s infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT IX – INFRINGEMENT OF THE '297 PATENT

102. Plaintiff Helsinn re-alleges paragraphs 1-101 as if fully set forth herein.

103. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '297 patent, Gland has infringed one or more claims of the '297 patent under 35 U.S.C. § 271(e)(2)(A).

104. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '297 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '297 patent.

105. Upon information and belief, Gland was aware of the existence of the '297 patent and is aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '297 patent.

106. Upon information and belief, Gland is aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '297 patent would constitute an act of infringement of one or more claims of the '297 patent.

107. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112 and a blanket denial of a specific intent to provide therapeutically effective blood levels of palonosetron and netupitant, Gland's Notice Letters do not identify any factual bases for, or position regarding, noninfringement of claims 1-23 of the '297 patent.

108. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's

ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '297 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

109. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '297 patent, including any later expiration of exclusivity for the '297 patent to which Helsinn is or becomes entitled.

110. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT X – INFRINGEMENT OF THE '698 PATENT

111. Plaintiff Helsinn re-alleges paragraphs 1-110 as if fully set forth herein.

112. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '698 patent, Gland has infringed one or more claims of the '698 patent under 35 U.S.C. § 271(e)(2)(A).

113. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '698 patent, would infringe and/or induce and/or contribute to the infringement of the '698 patent.

114. Upon information and belief, Gland is aware of the existence of the '698 patent and is aware that the submission of Gland's ANDA No. 217374 to the FDA constitutes an act of infringement of one or more claims of the '698 patent.

115. Upon information and belief, Gland is aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of

Gland's ANDA Product before the expiration of the '698 patent would constitute an act of infringement of one or more claims of the '698 patent.

116. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-6 of the '698 patent.

117. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '698 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

118. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '698 patent, including any later expiration of exclusivity for the '698 patent to which Helsinn is or becomes entitled.

119. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. a Judgment that Gland has infringed one or more claims of the patents-in-suit by submitting ANDA No. 217374 to the FDA;

B. a Judgment that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product will infringe, and/or induce and/or contribute to the infringement of, one or more claims of the patents-in-suit;

C. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 217374 be a date that is not earlier than the expiration date of the latest-expiring patent of the patents-in-suit, including any later expiration of exclusivity for the patents-in-suit to which Helsinn is or becomes entitled;

D. a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283, restraining and enjoining Gland, its directors, officers, agents, attorneys, affiliates, divisions, successors, and employees, and those acting in privity or concert with them, from engaging in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of any drug product, or use thereof, claimed in the patents-in-suit;

E. a Judgment that this case is exceptional and that Plaintiff is entitled to its reasonable attorney fees pursuant to 35 U.S.C. § 285; and

F. such other and further relief as the Court may deem just and proper.

Dated: July 18, 2022

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Helsinn Healthcare S.A.

OF COUNSEL:

Eric W. Dittmann
Isaac S. Ashkenazi
Melanie R. Rupert
Dana Weir
M. Ryan Meuth
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: July 18, 2022

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Helsinn Healthcare S.A.

OF COUNSEL:

Eric W. Dittmann
Isaac S. Ashkenazi
Melanie R. Rupert
Dana Weir
M. Ryan Meuth
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166